

REMARKS

Claims 6, 8, 9, and 19-23 are pending. Claims 1-5, 7, and 10-18 were canceled previously. In the present amendment, Applicants amend claims 6, 8, and 19-22, and add new claim 24 as described below. Following entry of the present amendment, claims 6, 8, 9, and 19-24 are pending and under examination.

Independent claims 8 and 22 have each been amended to recite “[a] method of identifying the differentiation state of a test cell, test tissue, or test nucleus, wherein the test cell, test tissue, or test nucleus is selected from a stem cell, a stem cell tissue, a stem cell nucleus, a differentiating stem cell, a differentiating stem cell tissue, a differentiating stem cell nucleus, a cell differentiated from a stem cell, a tissue differentiated from a stem cell tissue, and a nucleus differentiated from a stem cell nucleus. . . .” In addition, claim 8 has been amended to recite “. . . obtaining a differentiation state-specific DNA methylation pattern for one or more cell, tissue, or nucleus of known differentiation state, wherein the one or more cell, tissue, or nucleus of known differentiation state is selected from a stem cell, a stem cell tissue, a stem cell nucleus, a differentiating stem cell, a differentiating stem cell tissue, a differentiating stem cell nucleus, a cell differentiated from a stem cell, a tissue differentiated from a stem cell tissue, and a nucleus differentiated from a stem cell nucleus. . . .”

Those amendments merely alter the grammar of the claim language to eliminate possible inaccurate interpretations of the phrase, “differentiated stem cell,” without changing the scope of the claims as previously presented. No new matter has been added.

Moreover, although the phrase “differentiating stem cell” does not expressly appear in the present application, the phrase is implicit throughout the specification. The specification teaches, for example, that “the method of the present invention will still be able to contribute to the evaluation of safety of the produced stem cells when transplanted or to the improvement of

efficiency of the cell production by determining whether the produced cells are stem cells or not by evaluating the degree of the stem cells.” Specification at page 13, lines 21-26. In context, it is clear that the phrase, “the degree of the stem cells,” refers to cells that are in the process of differentiating from undifferentiated stem cells or are differentiated. Accordingly, no new matter has been added by this language.

Similarly, although the phrase “cell differentiated from a stem cell” does not expressly appear in the present application, the phrase is implicit throughout the specification. The specification teaches, for example, that “if the production of differentiated ES cells is intended, undifferentiated ES cells may be cultured after random methylation of genes thereof. The cultivation is carried out in a medium . . . according to conventional animal cell culture techniques. Subsequently, the resultant cells are subjected to random demethylation.” Specification at page 12, line 30, to page 13, line 5. It is clear from that quote that undifferentiated ES cells are cultured to produce “resultant cells,” which are “differentiated.” Thus, “resultant cells” are cells differentiated from ES cells. Accordingly no new matter has been added by this language.

In addition, claims 6, 8, 19, 20 21, and 22 have deleted the language “stem” and “stem cell” as indicated in the amendments to promote claim language consistency. Also, claim 19 has been amended to recite “differentiating embryonic stem cell, differentiating embryonic stem cell tissue, differentiating embryonic stem cell nucleus, a cell differentiated from an embryonic stem cell, a tissue differentiated from an embryonic stem cell tissue, or a nucleus differentiated from an embryonic stem cell nucleus,” and claim 22 has been amended to recite “differentiating embryonic stem cell,” “cell differentiated from embryonic stem cell,” “differentiating trophoblast stem cell,” and “cell differentiated from trophoblast stem cell.” Those amendments promote

claim language consistency and, as discussed above, are implicit in the specification.

Accordingly, no new matter has been added.

Finally, new claim 24 depends from claim 8 and includes the language “wherein the differentiation state of the one or more cell, tissue, or nucleus of known differentiation state is differentiating.” New claim 24 is consistent with the claim language and amendments discussed above and, as discussed above, includes language implicit in the specification. Accordingly, no new matter has been added.

Rejection of Claims 6, 8, 9, and 19-23 Under 35 U.S.C. § 112, First Paragraph

In the Advisory Action, the Examiner indicated that the rejection of claims 6, 8, 9, and 19-23 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement would be maintained. Advisory Action at page 2. Applicants respectfully traverse that rejection.

The Examiner acknowledged that “Applicants also argue that the specification provides guidance on how to create a differentiated stem cell. However, the Examiner is stating that, by definition, a stem cell cannot be differentiated and thus one of skill in the art is not enabled to create a differentiated stem cell.” *Id.* Applicants respectfully point out that the term “differentiated” can be used grammatically in a number of different ways. For example, it can be used as an adjective or as a verb form. Applicants respectfully note that the Examiner’s quoted statement illustrates this point. While it appears that the Examiner uses the term “differentiated” in the phrase, “differentiated stem cell,” as an adjective, e.g., to describe a type of stem cell, the Examiner’s use of the term “differentiated” in the phrase “a stem cell cannot be differentiated” is more open to interpretation. For example, if the use of “differentiated” in that phrase is interpreted not as an adjective, but as a verb form, then the Examiner’s quote “a stem cell cannot be differentiated,” could mean that it is not possible for a stem cell to undergo differentiation, or,

in other words, “a stem cell cannot be differentiated” into progeny. The Examiner will certainly recognize that such an interpretation of the quoted phrase, while grammatically proper, is contrary to the knowledge in the art. As the Examiner is no doubt aware, it is well known in the art that stem cells are “capable of . . . the production of a large number of differentiated, functional progeny.” Potten et al., Development 110: 1001-1020, 1990, at page 1002.

In view of such varying grammatical usages and possible differing interpretations of the term “differentiated,” and solely to expedite prosecution and without acquiescing to the Examiner’s contentions, Applicants have amended the claims to remove the language “differentiated stem cells” while maintaining the scope of the claims as presented in the Amendment and Response filed June 6, 2006. Claims 8 and 22 now recite “[a] method of identifying the differentiation state of a test cell, test tissue, or test nucleus, wherein the test cell, test tissue, or test nucleus is selected from a stem cell, a stem cell tissue, a stem cell nucleus, a differentiating stem cell, a differentiating stem cell tissue, a differentiating stem cell nucleus, a cell differentiated from a stem cell, a tissue differentiated from a stem cell tissue, and a nucleus differentiated from a stem cell nucleus. . . .” Claim 8 also recites “. . . obtaining a differentiation state-specific DNA methylation pattern for one or more cell, tissue, or nucleus of known differentiation state, wherein the one or more cell, tissue, or nucleus of known differentiation state is selected from a stem cell, a stem cell tissue, a stem cell nucleus, a differentiating stem cell, a differentiating stem cell tissue, a differentiating stem cell nucleus, a cell differentiated from a stem cell, a tissue differentiated from a stem cell tissue, and a nucleus differentiated from a stem cell nucleus. . . .” In addition, claim 19 has been amended to similarly recite “differentiating embryonic stem cell, differentiating embryonic stem cell tissue, differentiating embryonic stem cell nucleus, a cell differentiated from an embryonic stem cell, a tissue differentiated from an embryonic stem cell tissue, or a nucleus differentiated from an embryonic

stem cell nucleus,” and claim 22 has been amended to recite “differentiating embryonic stem cell,” “cell differentiated from embryonic stem cell,” “differentiating trophoblast stem cell,” and “cell differentiated from trophoblast stem cell.”

As discussed above, those amendments merely alter the grammar of the claim language to eliminate possible inaccurate interpretations of the phrase “differentiated stem cell.” And, as discussed above, the phrase “differentiating stem cell” is implicit throughout the specification. As noted above, the specification teaches, for example, that “the method of the present invention will still be able to contribute to the evaluation of safety of the produced stem cells when transplanted or to the improvement of efficiency of the cell production by determining whether the produced cells are stem cells or not by evaluating the degree of the stem cells.” Specification at page 13, lines 21-26. In context, it is clear that the phrase, “the degree of the stem cells,” refers to cells that are in the process of differentiating from undifferentiated stem cells or are differentiated.

Likewise, as discussed above, the phrase “cell differentiated from a stem cell” is implicit throughout the specification. As noted above, the specification teaches, for example, that “if the production of differentiated ES cells is intended, undifferentiated ES cells may be cultured after random methylation of genes thereof. The cultivation is carried out in a medium . . . according to conventional animal cell culture techniques. Subsequently, the resultant cells are subjected to random demethylation.” Specification at page 12, line 30, to page 13, line 5. It is clear from that quote that undifferentiated ES cells are cultured to produce “resultant cells,” which are “differentiated.” Thus, “resultant cells” are cells differentiated from ES cells.

Furthermore, Applicants assert that, considering the specification as a whole and the understanding of one skilled in the art at the time the application was filed, one skilled in the art would understand the phrase “differentiated stem cells” in the present English translation of the

Japanese priority application to refer to cells that are in the process of differentiating or are differentiated, according to the claimed methods. Accordingly, express references to "differentiated stem cells" throughout the specification, at least some of which were discussed at length in the Response filed on November 20, 2006, the discussion and arguments of which are hereby incorporated by reference, enable the full scope of the claims. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 6, 8, 9, and 19-23 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

CONCLUSION


In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of the application and the timely issuance of a Notice of Allowance. If the Examiner does not consider the claims allowable, the undersigned requests that, prior to taking action, the Examiner call her at (650) 849-6749 to set up an interview.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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